AND 2 MES

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Remarks/Arguments:

Summary of Changes Made

By this Amendment, claims 9-20 and 28-35 have been canceled. Thus, claims 1-8 and 21-27 are pending in the application.

Election/Restrictions

Although the Examiner has cited the PCT Rules, counsel for applicant hereby submits that the Examiner has not applied the appropriate standard in determining whether more than one invention is presented by the claims of the present application. In this regard it is noted that restriction practice in the U.S. is not directly related to "unity" practice under the PCT. It is further noted that species/genus practice in the U.S. does not exist in international applications, and cannot be applied to national stage applications in the U.S. Applicant further notes that the "unity" of the claims was implicitly acknowledged during the international phase by the ISA. Accordingly, it is submitted that under Article 27 of the PCT and 37 CFR §1.475, the USPTO cannot now properly require restriction. For this reason alone, the Examiner is asked to reconsider and withdraw the restriction requirement.

Notwithstanding the foregoing, and without waiving the right to traverse future restriction requirements that may be asserted in any divisional/continuation applications that may subsequently be filed, applicant has complied with the Examiner's restriction requirement by electing SET I (claims 1-8 and 21-27), as identified by the Examiner in the prior Office Action. All claims drawn to the non-elected subject matter have been canceled (i.e., claims 9-20 and 28-35).

Also in the prior Office Action, the Examiner stated on page 2 that "election of a SET will not be considered a correct response to the restriction requirement. Applicants are only allowed to elect on Group from one SET". The Examiner's contention regarding this issue is contrary to well-settled law.

In *In re Weber*, 580 F.2d 455, 459-460 (C.C.P.A. 1978), the Court rejected the proposition that a single claim, whether expressed using *Markush* language or otherwise, could be subject to restriction under 35 U.S.C. §121. The Court reasoned that (citations omitted):

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount. We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

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The M.P.E.P. rules pertaining to *Markush* style claims and restriction requirements were changed to accommodate the *Weber* decision. M.P.E.P. §803.02 now provides that:

If the members of the *Markush* group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the *Markush* group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a *Markush* group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

This subsection deals with *Markush*-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the *Markush*-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a *Markush*-type claim drawn to the compound C-R, wherein R is a radical selected from

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the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The *Markush*-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the *Markush*-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the *Markush*-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the *Markush*-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markushtype claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

In the present application, claims 1-3 and 5-8 are *Markush*-type claims. As is noted in the application, the members of the Markush grouping have common utility and are all members of a recognized class of chemical compounds, namely peptides.

Restriction cannot lawfully be applied with respect to applicant's individual claims. In accordance with M.P.E.P. §803.02 and the case law giving rise to it, applicants hereby provisionally elect the specifies identified by SEQ ID 1 for examination.

Conclusion

In view of the foregoing, claims 1-8 and 21-27 are believed to be in condition for allowance. The issuance of a timely Notice of Allowance is therefore respectfully requested.

Respectfully submitted,

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